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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VOGEL, NANCY S	
ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/763,011	CONTRERAS,	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/11/06 (arguments), 4/24/07(claims)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-9,15-17 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2 and 4* is/are allowed.

6)☒ Claim(s) *1, 2, 4, 6-9, 15-17 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2 , 4, 6-9, 15-17 and 35 are pending in the case.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-9, 15-17, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 1/12/06.

Applicant's arguments filed 4/11/06 have been considered but have not been found convincing.

Applicants have argued that they have amended claim 1 "to recite SEQ ID NO:1" and have amended claim 2 "to recite sequences that have at least 90% homology to SEQ ID NO:1". Applicants state that there is support in the specification for these amendments. Although there is literal support for the claim amendments in the specification, i.e. the words "at least 90% homology to SEQ ID NO:1", it is maintained that the specification does not provide adequate support for the genus of nucleic acids

having the specified level of homology, and the function of being critical for survival and growth in C. albicans. Although the claim 2 has been amended to eliminate language referring to fragments and derivatives, the claims still encompass variants having at least 90% homology to SEQ ID NO:1. Therefore, as was stated before, the claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More particularly, the claims are directed to a genus of nucleic acid molecules, wherein said genus is comprised of a subgenus of nucleic acid molecules having at least 90% homology to SEQ ID NO: 1. Said nucleic acid molecules (i.e., structures) must correlate to a function of encoding a polypeptide that is "critical for survival and growth of the yeast Candida albicans". Given the size of SEQ ID NO: 1, even where limited to nucleic acid molecules that are 90% homologous the genus comprises tens of thousands of potential nucleic acid molecules.

The critical feature in the instant claims is the nucleic acid structure as claimed and having the prescribed function of encoding a critical protein. Therefore, in the context of the instant claims, a sufficient description would identify a representative number of nucleic acid molecules that are at least 90% homologous to SEQ ID NO: 1, and correlate to function of encoding a protein that is itself critical for C. albicans survival and growth. The specification does not identify a representative number of embodiments comprised in the genus/subgenus of claimed nucleic acid molecules. The specification discloses that SEQ ID NO: 1 encodes the protein SAM2 (e.g.,

Specification, p. 35), but there is no further clarification of particular domains, motifs, sequences, or any other structural feature, that can be identified as a necessary sequence that encodes a necessary portion of a protein that is critical for both survival and growth. No regions are disclosed that are at least 90% homologous to SEQ ID NO: 1 and that maintain the function of encoding a critical polypeptide or domains thereof. Therefore, the rejection is maintained.

The following is a new rejection necessitated by applicant's amendment:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and by dependence, claims 6-9, 15-17, and 35 is vague and indefinite since it is not clear what is intended by the language, "An isolated nucleic acid molecule encoding a polypeptide which is critical for survival and growth of the yeast Candida albicans and wherein the nucleic acid molecule has a nucleic acid sequence that is at least 90% homologous to said isolated nucleic acid molecule having a sequence comprising SEQ ID No: 1". It is not clear what is intended due to the numerous recitations of "nucleic acid molecule" which make it unclear what the identity of the claimed nucleic acid molecule is intended to be. Presumably, it is intended that isolated nucleic acid molecules having at least 90% homology to SEQ ID NO:1, and which are critical for survival and growth

of the yeast Candida albicans, however, this is not clear in the claim.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 6-9, 15-17, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinstock et al. (US Patent 6,747,137).

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 1/12/06.

As is noted above, it is not clear exactly what is intended to be encompassed by claim 1, and therefore, it is maintained that the claim could be interpreted to encompass nucleic acid molecules that comprise a fragment having at least 90% homology to any span or region of SEQ ID NO: 1 or having from 10 to 50 contiguous nucleic acid sequences of any span or region of SEQ ID NO: 1.

The reference ('137) discloses nucleic acids which contain regions which are the nucleic acid molecule of SEQ ID NO: 5972, which is 81% homologous over the entire length of SEQ ID NO: 1. (e.g., col. 1272; col. 7, 11.35-45; col. 8, 11. 5-20; col. 26). However, within the span or regions of SEQ ID NO: 1, there are portions that are at least 90% identical (e.g., 100% identity) to portions or regions of SEQ ID NO: 1. In other words, as written the limitation homologous is not relative to the entire length of SEQ ID NO: 1. Furthermore, within the regions of identity (i.e., sequences encompassed by SEQ 1D NO: 5972), there are contiguous stretches of 10-50 nucleotides that meet the claimed limitations of claim 35.

Applicant's arguments filed 4/11/06 have been considered but have not been found convincing.

Applicant's have argued that they have removed the homology that would otherwise overlap the subject matter of the '137 patent. However, the amendment that has been made to claim 1 does not remove said homology, for the reasons set forth above. Therefore the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-9, 15-17 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-21 and 23-28 of copending Application No. 10/451,467. Although the conflicting claims are not

identical, they are not patentably distinct from each other because while the claims do not recite the same exact limitations, they are directed to indistinguishable subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 1/12/06.

Applicant's arguments filed 4/11/06 have been considered but have not been found convincing.

Applicants have argued that the they have removed homology that would overlap the cited application. However, as is noted above, it is not clear exactly what is intended to be encompassed by claim 1, and therefore, it is maintained that the claim could be interpreted to encompass nucleic acid molecules that comprise a fragment having at least 90% homology to any span or region of SEQ ID NO: 1 or having from 10 to 50 contiguous nucleic acid sequences of any span or region of SEQ ID NO: 1. Furthermore, it is noted that the previous version of claim 1 also recited 90% homology. Therefore, the provisional rejection is maintained.

Conclusion

Claims 2 and 4 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV
6/28/07

NANCY VOGEL
PRIMARY EXAMINER